AUG - 8 2011 K112059 1/2

510(k) Summary of Safety and Effectiveness:
T2 Nail

Proprietary Name: **Common Name:**	T2 Femoral Nail Intramedullary Nail, Femoral Nail
Classification Name and Reference:	Intramedullary Fixation Rod, 21 CFR §888.3020
Proposed Regulatory Class:	Class II
Product Codes:	HSB
For Information contact:	Valerie Giambanco Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6275 Fax: (201) 831-3275
Date Prepared:	7/15/2011

Legally Marketed Device to Which Substantial Equivilance is Claimed:

T2 Femoral Nail System: K081152, K021744, K014220, K010801

Description:

The T2 Femoral nail is a cylindrical, cannulated titanium alloy tube, slightly bowed to accommodate the shape of the femur. The T2 Femoral Nail may be inserted into the femoral canal using either a retrograde or antegrade surgical approach. The T2 Femoral Nail is currently available in diameters ranging from 8 to 15 mm and lengths ranging from 140 to 480 mm.

Additional sizes will offer 16 and 17 mm diameters.

Intended Use:

The modifications do not alter the intended use of the predicate system as cleared in the referenced premarket notifications. The T2 Femoral Nail System is a fracture fixation device comprised of femoral nails and the related locking screws, compression screws, and end caps. The T2 Femoral Nail System is intended to provide strong and stable internal fracture fixation with minimal soft tissue irritation. This device is utilized as an aid to healing, not as a substitute for normal intact bone and tissue.

Indications for Use:

The T2 Femoral Nail is indicated for long bone fracture fixation specifically femoral fracture fixation, which may include the following:

- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Supracondylar fractures, including those with intra-articular extension
- Ipsilateral femur fractures
- Fractures proximal to a total knee arthroplasty
- Fractures distal to hip joint
- Nonunions and malunions

Proposed Modification:

The subject T2 Femoral Nails have the same indications for and intended use, material, and operational principles as the previously cleared T2 Femoral Nails cleared under K081152, K021744, K014220, and K010801. The subject T2 Femoral device consists of additional, larger diameter sizes of 16 and 17mm. The lengths will continue to range from 140-480mm in 20mm increments for the nails with a radius of 3m and lengths of 240-480mm for the nails with a radius of 1.5m.

Summary of Data:

Mechanical testing has been performed on the worst case predicate T2 Femoral Nail. Engineering analysis demonstrates the increased diameter of the T2 femoral nail produces substantially equivalent subject devices based on component strength, moment of inertia and stresses experienced. Thus, the engineering analysis of the new 16 and 17mm diameter sizes demonstrates that the additional sizes do not affect the safety and effectiveness of the device. Potential risks analyzed include anatomical fit of the new diameter. These risks have been investigated with use of failure mode effect analysis (FMEA) and mechanical testing which analyzed the strength of the device and demonstrate how the proposed diameters do not affect device performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp.
% Ms. Valerie Giambanco
325 Corporate Drive
Mahwah, New Jersey 07430

AUG - 8 2011

Re: K112059
Trade/Device Name: T2 Femoral Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: July 15, 2011
Received: July 19, 2011

Dear Ms. Giambanco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112059

Device Name: T2 Femoral Nail

Indications for Use:

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- Fractures distal to hip joint
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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112059